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CONFIRMATION NO. ATTORNEY DOCKET NO. FIRST NAMED INVENTOR FILING DATE APPLICATION NO. RPA1002 Sheng-Yung Pai Chang 12/16/1999 09/465,491

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ROCHE MOLECULAR SYSTEMS INC PATENT LAW DEPARTMENT 1145 ATLANTIC AVENUE ALAMEDA, CA 94501

EXAMINER GOLDBERG, JEANINE ANNE PAPER NUMBER ART UNIT 1655

DATE MAILED: 01/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
		CHANG ET AL.
Advisory Action	09/465,491	Art Unit
•	Examiner Jeanine A Goldberg	1655
The MAILING DATE of this communication app	pears on the cover sheet with the	
THE REPLY FILED 20 December 2001 FAILS TO PLA Therefore, further action by the applicant is required to a final rejection under 37 CFR 1.113 may only be either: (condition for allowance; (2) a timely filed Notice of Appe Examination (RCE) in compliance with 37 CFR 1.114. PERIOD FOR F	CE THIS APPLICATION IN CON avoid abandonment of this application 1) a timely filed amendment which all (with appeal fee); or (3) a time REPLY [check either a) or b)]	eation. A proper reply to a ch places the application in all filed Request for Continued
b) The period for reply expires on: (1) the mailing date of the no event, however, will the statutory period for reply expire ONLY CHECK THIS BOX WHEN THE FIRST REPLY W 706.07(f). Extensions of time may be obtained under 37 CFR 1.136(a). The fee have been filed is the date for purposes of determining the period fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date (2) as set forth in (b) above, if checked. Any reply received by the Country timely filed, may reduce any earned patent term adjustment. See 3	The date on which the petition under 37 C and of extension and the corresponding ar of the shortened statutory period for reportice later than three months after the materials of the shortened statutory period for reportice later than three months after the materials of the shortened statutory period for reportice later than three months after the materials of the shortened statutory period for the shortened statutory period for reportice later than three months after the materials of the shortened statutory period for the shortened statutory period statutory period statutory period statutory period statutory period statutory period statu	CFR 1.136(a) and the appropriate extension mount of the fee. The appropriate extension ly originally set in the final Office action; or nailing date of the final rejection, even if
37 CFR 1.192(a), or any extension thereof (or s	d because:	
2. ☑ The proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment(s) this rest is a large state of the proposed amendment (s) the proposed amendme		
(b) ☐ they raise the issue of new matter (see Note below); (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the		
(c) ☐ they are not deemed to place the application issues for appeal; and/or	on in better form to appear by me	of finally rejected claims.
issues for appeal; and/or (d) they present additional claims without can	celing a corresponding number of	of many rejected t
NOTE: See Continuation Sheet.		
3. Applicant's reply has overcome the following rejection(s):		
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment		
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does to a place and the plac		
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were normal to fine trainering.		
7. For purposes of Appeal, the proposed amenda explanation of how the new or amended claim	ing would be to just the	or b) will be entered and an below or appended.
The status of the claim(s) is (or will be) as follows:		
Claim(s) allowed: <u>NONE</u> .		
Claim(s) objected to: NONE.		
Claim(s) rejected: <u>1,3,5-8,10,12-21,23 and 25-27</u> .		
s and antion: NONE		
a The proposed drawing correction filed on is a) approved or b) disapproved by with a		
9. Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s)		
10. Other:		
10.		

Continuation Sheet (PTO-303)

Continuation of 2. NOTE:



The response amends Claim 21 to recite using a pair of primers which are capable of hybridizing within exon 8 or downstream of exon 8 of the hTERT gene and a second primer capable of hybridizing upstream of exon 8 of the hTERT gene. The newly amended claim contains limitations which were not previously searched. The originally filed Claim 1 required using a primer which is within exon 8 and was subsequently amended to require specific primers. The newly amended claims do not require such a limitation, but have broadended the claim to allow for any primer which is downstream of exon 8. Moreover, the amendment does not appear to be directed to the invention as described in the specification such that it is critical that the primer be placed in the beta-deletion. Further, as argued by the response in Paper number 6, filed December 21, 2000 in response to the office action of August 28, 2000, "One of the critical aspect of the methods is the use of a primer that hybridizes within exon 8, which is a particular sub-region wihtin the beta-region" (page 10). The newly amended claims no longer reuire this "critical aspect of the invention".

Additionally, search and consideration would be required for the addition of the comparsion to a control sample which was not previously provided in the claim.

The claim has also added "capable of hybridizing" however, it is unclear as to capable of hybridizing under what conditions.

Finally, the response cancels the previously pending kit claims and replaces them with much broader kit claims which have not been searched nor considered. Previoulsy the kit claims required specific sequences, such as SEQ ID NO: 2, 4 and 5. The newly added kit claim 38 is directed to any primer pair which is capable of hybridizing within exon 8 or downstream of exon 8 of the hTERT gene and a seoned primer capable of hybridizing upstream of exon 8. In essence, a pair of primers which amplified the entire gene would anticipate the proposed claim. The newly added kit claims also contain a set of instructions which was not previously presented.

Continuation of 5. does NOT place the application in condition for allowance because:

The arguments are drawn to the newly proposed claims which have not been entered. .

Supervisory Patent Examiner **Technology Center 1600**